

REMARKS

Claims 23-35, 38, 41-47, and 59-78 are pending. Claims 23, 24, 27, 60, 64, 65, and 77 are amended herein. Claim 79 is added. Support for the amendments to claims and added claims is found throughout the Specification and claims, as filed, and no new matter is presented by the amendment (e.g. see page 6, lines 13-14/Fig. 4 description; page 11, last paragraph – page 8 first paragraph; page 14, lines 11-17).

Favorable reconsideration in light of the amendments are remarks which follow a respectfully requested.

Applicant wishes to thank the Examiner for the courtesy of an interview conducted on October 5, 2005 with Applicant's representatives. During the interview, the rejections of the claims were discussed, and potential claim amendments were also discussed.

1. 35 U.S.C. §102 Rejections

Paques et al.

Claims 23-30, 32, 33-40, 42-44, 47-52, 54, 55, 58-65, 67-69, and 72-78 are rejected under 35 U.S.C. §102(e) over Paques et al. (US Pub 2003/0171722). Applicants respectfully traverse.

Claim 23

Applicants claim in claim 23, a method for treating an eye comprising inserting into an eye a device comprising a piercing member and a cannula slidably disposed within the piercing member, wherein the step of inserting the device into the eye comprises penetrating the eye with the piercing member and advancing the piercing member through the eye, advancing the cannula through the piercing member towards a treatment site, piercing the treatment site with the cannula, and treating the eye by administering and/or aspirating material through the cannula.

Applicants respectfully submit that Paques et al. does not teach or suggest a method wherein the device is inserted into the eye by penetrating the eye with a piercing member of the device and advancing the piercing member through the eye as claimed by Applicants. Rather, according to Paques' method:

The instrument of Figs. 1-3 is used to introduce the needle 4 and the distal end 14d of the optical fiber 14 into the eye through a sclerotomy [0048] lines 3-6; [0108 lines 3-6]

Thus, Paques' method requires that a sclerotomy (surgical incision) be made in the eye prior to introduction of the device into the eye through the pre-made sclerotomy.

Applicants further submit that Paques et al. does not teach or suggest a method wherein a cannula is advanced through a piercing member towards a treatment site to pierce the treatment site with the cannula as claimed by Applicants. Rather, Paques device includes a hand piece 2 having a proximal end 2p graspable by a physician, and a distal end 2d carrying a hollow needle 4. (See, e.g. [0100, lines 1-4]). Paques et al. does not teach or suggest a hollow needle slidably disposed in an outer piercing member. Further Paques et al. does not teach or suggest anywhere a method wherein the hollow needle is advanced through an outer member towards a treatment site.

Accordingly, claim 23 is patentable over Paques et al. Claims 24-26, 38, 41-47, 74, and 77 depend from claim 23 and, likewise, are patentable over Paques et al. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 27

Applicants claim, in claim 27, a method of treating an eye, comprising piercing the eye with a piercing member and inserting the piercing member into the vitreous humor of the eye, the piercing member having a proximal end and a distal end and a lumen defined therebetween,

angling the piercing member in any direction so as to guide the cannula to any treatment site within the eye, advancing a cannula through the piercing member lumen and beyond the distal end of the piercing member, guiding the cannula through the vitreous humor of the eye to the treatment site, and treating the treatment site.

As set forth above with respect to claim 23, Paques et al. does not teach or suggest a method wherein the device is inserted into the eye by piercing the eye with a piercing member as claimed by Applicants. As further set forth above with respect to claim 23, Paques et al. does not teach or suggest a method wherein a cannula is advanced through an outer piercing member lumen and beyond the distal end of the piercing member and guided to a treatment site.

Further, Applicants respectfully submit that Paques et al. does not teach or suggest a method wherein the piercing member is angled in any direction so as to guide the cannula to any treatment site within the eye. Nowhere in Paques et al. is angling of a piercing member described or suggested. Further, nowhere in Paques et al. is a method taught or suggested wherein the piercing member is angled to guide the cannula (which is subsequently advanced through the piercing member lumen to a treatment site) to any treatment site within the eye.

Accordingly, claim 27 is patentable over Paques et al. Claims 28-35, 49-59, 75, and 79 depend from claim 27 and, likewise, are patentable over Paques et al. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 60

Applicants claim, in claim 60, a method for treating an eye comprising inserting into an eye a device comprising an outer member having a proximal end and a distal end, a cannula slidably disposed within the outer member, and a piercing member at the distal end of the outer member, wherein the step of inserting the device into the eye comprises piercing the eye with the piercing member and advancing the piercing member and at least a portion of the outer member

into the eye, advancing the cannula through the outer member and beyond the distal end to the treatment site, and treating the eye by administering and/or aspirating material through the cannula.

As set forth above with respect to claim 23, Paques et al. does not teach or suggest a method wherein the device is inserted into the eye by piercing the eye with a piercing member and advancing the piercing member and at least a portion of the outer member into the eye as claimed by Applicants. As further set forth above with respect to claim 23, Paques et al. does not teach or suggest a method wherein a cannula is advanced through an outer piercing member and beyond the distal end of the piercing member to a treatment site.

Accordingly, claim 60 is patentable over Paques et al. Claims 61-73 and 76-78 depend from claim 60 and, likewise, are patentable over Paques et al. Reconsideration and withdrawal of the rejection is respectfully requested.

Josephberg

Claims 23-35, 38, 41-47, and 59-76 are rejected under 35 U.S.C. §102(b) over Josephberg (USPN 5,989,262). Applicants respectfully traverse.

Claim 23

Applicants respectfully submit that Josephberg does not teach or suggest a method wherein a cannula is advanced through an outer piercing member towards a treatment site, the treatment site is pierced with the cannula, and the eye treated by administering and/or aspirating material through the cannula as claimed by Applicants in claim 23.

Josephberg describes a device and method wherein a guillotine cutter is inserted into the eye. The cutter includes an inner cutter 70 and an outer cutter assembly 44. Outer cutter assembly includes tubing 58 having aperture. Inner cutter has a sharpened cutting edge 80.

Inner cutter is provided with a return spring 82 such that sharpened cutting edge 80 of the inner cutter 70 is capable of movement back and forth across the aperture 60 of tubing 58. (See col. 3, line 64-col. 4, line 3; Figs. 2, 3a and 3b). The device is inserted into the eye, and the cutter is actuated so that inner cutter 70 moves across an aperture 60 in tubing 58. The inner cutter 70 is cycled at an appropriate speed back and forth across aperture 60 so that each time a cutting edge 80 of the inner cutter 70 moves across aperture, a portion of the vitreous is sliced off and drawn into the device to sample chamber 116 (See figures and col. 5, lines 7-39).

Josephberg, however, does not teach or suggest a method wherein the cannula (inner cutter) is advanced through piercing member (outer cutter) towards a treatment site, the treatment site pierced with the cannula, and the eye treated by administering and/or aspirating material through the cannula. Rather, Josephberg describes a method wherein an inner cutter is cycled in and out of outer cutter so as to capture and slice off portions of the vitreous.

Accordingly, claim 23 is patentable over Josephberg. Claims 24-26, 38, 41-47, 74, and 77 depend from claim 23 and, likewise, are patentable over Josephberg. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 27

Applicants respectfully submit that Josephberg does not teach or suggest a method wherein a piercing member is inserted into the vitreous humor of the eye and the piercing member angled in any direction so as to guide the cannula to any treatment site within the eye.

Nowhere in Josephberg is angling of a piercing member described or suggested. Further, nowhere in Josephberg is a method taught or suggested wherein the piercing member is angled to guide the cannula (which is subsequently advanced through the piercing member lumen to a treatment site) to any treatment site within the eye.

Accordingly, claim 27 is patentable over Josephberg. Claims 28-35, 49-59, 75, and 79 depend from claim 27 and, likewise, are patentable over Josephberg. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 60

Applicants respectfully submit that Josephberg does not teach or suggest a method for treating an eye comprising inserting into an eye a device comprising an outer member having a proximal end and a distal end, a cannula slidably disposed within the outer member, and a piercing member at the distal end of the outer member, the eye is pierced with the piercing member and the piercing member and at least a portion of the outer member are advanced into the eye, advancing the cannula through the outer member and beyond the distal end to the treatment site, and treating the eye by administering and/or aspirating material through the cannula.

As set forth above, Josephberg describes a method wherein an inner cutter 70 is cycled in and out across an aperture 60 in tubing 58 so that each time a cutting edge 80 of the inner cutter 70 moves across aperture, a portion of the vitreous is sliced off and drawn into the device to sample chamber 116 (See figures and col. 5, lines 7-39). For subsequent inspection and testing (see Abstract).

However, Josephberg does not teach or suggest a method wherein a cannula is advanced through an outer member and beyond the distal end to the treatment site, and the eye treated by administering and/or aspirating material through the cannula. Josephberg does not teach or suggest treatment of a site by administering or aspirating material through inner cutter.

Accordingly, claim 60 is patentable over Josephberg. Claims 61-73 and 76-78 depend from claim 60 and, likewise, are patentable over Josephberg. Reconsideration and withdrawal of the rejection is respectfully requested.

Trese

Claims 23-35, 38, 41-47, and 59-78 are rejected under 35 U.S.C. §102(b) over Trese (USPN 6,428,553). Applicants respectfully traverse.

Claim 23

Applicants respectfully submit that Trese does not teach or suggest a method wherein a device is inserted into the eye by penetrating the eye with a piercing member of the device and advancing the piercing member through the eye as claimed by Applicants. Applicants further submit that Trese does not teach or suggest a method wherein a cannula is advanced through an outer piercing member towards a treatment site, the treatment site pierced with the cannula, and the eye treated by administering and/or aspirating material through the cannula as claimed by Applicants in claim 23.

As set forth by Trese:

Ophthalmic surgery usually requires the introduction of instruments into the interior of the eyeball. An opening is formed in the eyeball and sometimes a cannula is inserted into the opening. Thereafter, instruments are inserted through the eye opening so that an end of the instrument is within the interior of the eyeball. (Col.

Trese describes an illuminated ophthalmic membrane pick assembly 10 comprising an elongated housing 12 which includes an elongated throughbore 14. An elongated tubular and cylindrical probe 20 is fixedly secured to the end 18 of the housing, and a membrane pick 30 is fixedly secured to the free or distal end 32 of the probe 20. The probe 20 is dimensioned for insertion through a cannula 24 (FIG. 2) into the interior 26 of an eyeball 28 (FIG. 2) (see col. 2, lines 51-56).

Thus, according to Trese, an opening is formed in the eye and a cannula inserted into the opening. Thereafter, Trese's instrument is inserted through the cannula, which does not form any portion of the device. Further, the membrane pick 30 is fixedly secured to the probe 20 which, in turn, is fixedly secured to the end of the housing. Thus the device of Trese does not, nor could it provide advancement of a cannula through an outer piercing member towards a treatment site. Still further, Trese does not teach or suggest piercing the treatment site with the cannula and treating the eye by administering and/or aspirating material through the cannula.

Accordingly, claim 23 is patentable over Trese. Claims 24-26, 38, 41-47, 74, and 77 depend from claim 23 and, likewise, are patentable over Trese. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 27

Applicants respectfully submit that Trese does not teach or suggest a method of treating an eye comprising piercing the eye with a piercing member and inserting the piercing member into the vitreous humor of the eye, angling the piercing member in any direction so as to guide the cannula to any treatment site within the eye, advancing a cannula through the piercing member lumen and beyond the distal end of the piercing member, guiding the cannula through the vitreous humor of the eye to the treatment site, and treating the treatment site.

As set forth with respect to claim 23, Trese describes making an opening in the eye and inserting a cannula into the opening. Thereafter, Trese's instrument is inserted through the cannula, which does not form any portion of the device. As further set forth with respect to claim 23, the membrane pick 30 of Trese is fixedly secured to the probe 20 which, in turn, is fixedly secured to the end of the housing. Thus the device of Trese does not, nor could it provide advancement of a cannula through an outer piercing member towards a treatment site. Still further, Trese does not teach or suggest piercing the treatment site with the cannula and treating the eye by administering and/or aspirating material through the cannula.

Still further, nowhere in Trese is angling of a piercing member described or suggested. Further, nowhere in Trese is a method taught or suggested wherein the piercing member is angled to guide the cannula (which is subsequently advanced through the piercing member lumen to a treatment site) to any treatment site within the eye

Accordingly, claim 27 is patentable over Josephberg. Claims 28-35, 49-59, 75, and 79 depend from claim 27 and, likewise, are patentable over Josephberg. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 60

Applicants respectfully submit that Trese does not teach or suggest a method for treating an eye comprising inserting into an eye a device comprising an outer member having a proximal end and a distal end, a cannula slidably disposed within the outer member, and a piercing member at the distal end of the outer member, the eye is pierced with the piercing member and the piercing member and at least a portion of the outer member are advanced into the eye, advancing the cannula through the outer member and beyond the distal end to the treatment site, and treating the eye by administering and/or aspirating material through the cannula.

As set forth above with respect to claim 23, Trese describes making an opening in the eye and inserting a cannula into the opening. Thereafter, Trese's instrument is inserted through the cannula, which does not form any portion of the device. As further set forth with respect to claim 23, the membrane pick 30 of Trese is fixedly secured to the probe 20 which, in turn, is fixedly secured to the end of the housing. Thus the device of Trese does not, nor could it provide advancement of a cannula through an outer piercing member towards a treatment site. Still further, Trese does not teach or suggest piercing the treatment site with the cannula and treating the eye by administering and/or aspirating material through the cannula.

Accordingly, claim 60 is patentable over Trese. Claims 61-73 and 76-78 depend from claim 60 and, likewise, are patentable over Trese. Reconsideration and withdrawal of the rejection is respectfully requested.

2. 35 U.S.C. 103 Rejections

Paques et al. and del Cerro

Claims 31, 45, 46, 56, 57, 70, and 71 are rejected under 35 U.S.C. 103(a) over Paques et al. in view of del Cerro et al. (USPN 5,409,457). Applicants respectfully traverse.

Claim 23

As set forth above with respect to claim 23, Paques' method requires that a sclerotomy (surgical incision) be made in the eye prior to introduction of the device into the eye through the pre-made sclerotomy. Further, Paques' hollow needle 4 is not slidably disposed in an outer member. Thus, Paques does not teach or suggest a method wherein the device is inserted into the eye by penetrating the eye with a piercing member of the device and advancing the piercing member through the eye as claimed by Applicants. Further, Paques does not teach or suggest a method wherein a cannula is advanced through an outer piercing member towards a treatment site, the treatment site pierced with the cannula, and the eye treated by administering and/or aspirating material through the cannula as claimed by Applicants in claim 23.

del Cerro does not remedy these deficiencies. del Cerro describes a device and method that is very different than that of Paques. del Cerro provides a device that is advanced inferior to the supraorbital ridge, superior to the eye, and in a caudal direction so as to reach the retina. del Cerro does not teach or suggest an outer piercing member with an inner cannula slidably disposed in the outer piecing member or a method wherein a cannula is advanced through an outer piercing member towards a treatment site, the treatment site pierced with the cannula, and the eye treated by administering and/or aspirating material through the cannula as claimed by Applicants in claim 23.

Thus, no combination of Paques et al and del Cerro teach or suggest applicants claim 23. Accordingly, claim 23 is patentable over Paques et al. and del Cerro. Claims 45 and 46 depend from claim 23 and, likewise, are patentable over Paques et al and del Cerro. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 27

As set forth above, Paques et al. does not teach or suggest a method wherein the device is inserted into the eye by piercing the eye with a piercing member, or wherein a cannula is advanced through an outer piercing member lumen and beyond the distal end of the piercing member and guided to a treatment site. As further set forth above, Paques et al. does not teach or suggest a method wherein the piercing member is angled in any direction so as to guide the cannula to any treatment site within the eye. Nowhere in Paques et al. is angling of a piercing member described or suggested. Further, nowhere in Paques et al. is a method taught or suggested wherein the piercing member is angled to guide the cannula (which is subsequently advanced through the piercing member lumen to a treatment site) to any treatment site within the eye.

del Cerro, as set forth above, does not teach or suggest an outer piercing member with an inner cannula slidably disposed in the outer piecing member or a method wherein a cannula is advanced through an outer piercing member lumen and beyond the distal end of the piercing member and guided to a treatment site as claimed by Applicants in claim 23.

Further, del Cerro does not teach or suggest a method wherein the piercing member is angled in any direction so as to guide the cannula to any treatment site within the eye. Nowhere in del Cerro is angling of a piercing member described or suggested. Further, nowhere in del Cerro is a method taught or suggested wherein the piercing member is angled to guide the

cannula (which is subsequently advanced through the piercing member lumen to a treatment site) to any treatment site within the eye.

Accordingly, claim 27 is patentable over Paques et al and del Cerro. Claims 31, 56, 57, and 79 depend from claim 27 and, likewise, are patentable over Paques et al and del Cerro. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 60

As set forth above, Paques et al. does not teach or suggest a method wherein the device is inserted into the eye by piercing the eye with a piercing member and advancing the piercing member and at least a portion of the outer member into the eye as claimed by Applicants. As further set forth above, Paques et al. does not teach or suggest a method wherein a cannula is advanced through an outer piercing member and beyond the distal end of the piercing member to a treatment site.

As further set forth above, del Cerro does not teach or suggest an outer piercing member with an inner cannula slidably disposed in the outer piecing member or a method wherein a cannula is advanced through an outer piercing member and beyond the distal end of the piercing member to a treatment site.

Accordingly, claim 60 is patentable over Paques et al and del Cerro. Claims 70 and 71 depend from claim 60 and, likewise, are patentable over Paques et al and del Cerro. Reconsideration and withdrawal of the rejection is respectfully requested.

Paques et al. and Bowman

Claims 41, 53, and 66 are rejected under 35 U.S.C. §103(a) over Paques et al. and Bowman et al. (USPN 6,378,526). Applicants respectfully traverse.

For the reasons set forth above, it is respectfully submitted that claims 23, 27, and 60 are patentable over Paques et al.

It is further submitted that Bowman et al. does not remedy the above-noted deficiencies in Paques et al. Bowman et al. is cited for the delivery of steroids, genetic material, or pharmaceuticals to the eye. However, Bowman et al. does not teach or suggest the devices or methods for treatment of the eye set forth independent claims 23, 27, and 60, from which claims 41, 53, and 66 depend.

Accordingly, claims 23, 27, and 60 are patentable over Paques et al. Claims 41, 53, 66, and 79 depend from claims 23, 27, and 60 and, likewise, are patentable over Paques et al and Bowman et al. Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

Applicant respectfully requests early consideration and allowance of the subject application.

Applicants believe that additional fees are not required in connection with the consideration of the within matter. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105**.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

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